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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/937,839	KANEDA, YASUFUMI
	<b>Examiner</b> Brian Whiteman	<b>Art Unit</b> 1635

**The MAILING DATE of this communication appears on the cover sheet with the correspondence address -**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 2/19/03.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-36 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 21 February 2002 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ . 6)  Other: *Seq. compliance letter.*

**DETAILED ACTION**

**Non-Final Rejection**

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be to directed to Brian Whiteman, Art Unit 1635.

Claims 1-36 are pending examination.

**Noncompliance**

**This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.**

**If the applicants do not comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures in the response to this office action, the response will be considered non-responsive.**

Applicant's traversal, the amendment to claims 1, 13-16, and 18-19, the amendment to the specification in paper no. 9 is acknowledged and considered.

***Election/Restrictions***

The election of the species (virus belonging to a Paramyxoviridae family) in paper no. 7 without traverse is acknowledged and remains final.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Drawings***

New corrected drawings are required in this application because of the objections set forth by the draftsperson. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Objections***

Claims 2-12 and 20-21 are objected to because of the following informalities: The phrase "A gene transfer vector according to claim .." is improper format for a dependent claim. Suggest replacing the phrase with -- The gene transfer vector according to claim ..(1, 5, 6, 11, 20) --. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13-16, 18-19, and claims dependent therefrom are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1, 13-16, and 18-19 filed on 2/19/03 introduce new subject matter into the disclosure. The application and the originally filed claims as a whole are directed to: A gene transfer vector containing a virus envelope.

Amended claim 1 for example, recites:

A gene transfer vector comprising an exogenous gene encapsulated in a virus envelope membrane.

The claimed invention as newly amended is directed to a vector comprising an exogenous gene encapsulated in a virus envelope membrane. However, the as-filed specification as a whole neither teaches nor suggests nor contemplates encapsulating an exogenous gene in a virus envelope membrane. In fact, the paragraph cited by applicant for support of the amended claims clearly indicates that applicant's claims are directed to a "gene transfer vector", "gene vector" or "virus envelope vector. See page 15 lines 11-15. The specification does not define a virus envelope membrane. The art of record teaches that a virus envelope membrane is a bilayer structure and is separated from the cytoplasm of the virus (US Patent 5,879,685, column 4, lines 28-32 and Lee et al. Virology 128:65-76, 1983 and Microbiology & Immunology: BS3035: Paramyxoviruses [online], 1/21/2003 [retrieved on 2003-04-09]. Retrieved from the Internet:<URL: <http://www-micro.msb.le.ac.uk/3035/paramyxoviruses.html>). In addition,

Art Unit: 1635

Figure 6 displays a plasmid DNA being incorporated into the cytoplasm of a HVJ envelope vector and not the envelope membrane of the vector.

It is apparent from the as-filed specification and the cited paragraph on page 15, that applicant at the time the invention was made did not intend or contemplate a gene transfer vector comprising an exogenous gene encapsulated in a virus envelope membrane. Thus, there is no evidence that the applicant was in possession of the invention of the base claims and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 13-16, 18-19 and claims dependent therefrom are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not teach how to make a gene transfer vector comprising an exogenous gene encapsulated in a virus envelope membrane. The specification states, "A method has also been reported in which reconstitution is carried out by adding new molecules...However, this method runs a high risk of losing the original viral function because the membrane composition of the completed particles is substantially different from that of the native virus particles. (see page 2, lines 25-32). The art of record does not disclose how to make

Art Unit: 1635

the claimed gene transfer vector. In view of the lack of guidance provided by the specification for the claimed invention, it would take one skilled in the art an undue amount of experimentation to reasonably correlate making a gene transfer vector containing a virus envelope to making a gene transfer vector comprising an exogenous gene encapsulated in a virus envelope membrane. Thus, in view of the In Re Wands Factors, one skilled in the art would not have been enabled to practice the claimed invention.

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 13-16, 18-19 and claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "virus envelope membrane" in claims 1, 13-16, 18-19 and claims dependent therefrom is a relative term, which renders the claims indefinite. The term "virus envelope membrane" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not define the metes and bounds of the term. The paragraph cited (See page 15 lines 11-15) by applicant for support of the term does not particularly point out and distinctly claim the subject matter which applicant regards as the invention. The definition in the art of record teaches that the virus envelope membrane of

Art Unit: 1635

a virus (Paramyxoviridae) is separated by the cytoplasm of the virus by the M protein layer (Microbiology & Immunology: BS3035: Paramyxoviruses [online], 1/21/2003 [retrieved on 2003-04-09]. Retrieved from the Internet:<URL: <http://www-micro.msb.le.ac.uk/3035/paramyxoviruses.html>). In view of the definition of the term in the art of record and the lack of a definition for the term in the specification, it is not apparent if the exogenous gene is encapsulated in the envelope membrane of the virus or in the cytoplasm of the virus. Therefore, the definition of the term is not defined by the specification.

Applicant's arguments with respect to Claims 1, 13-16, 18-19 and claims dependent therefrom have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 102***

Applicant's arguments, see paper no. 9, filed 2/19/03, with respect to the 102(e) rejection as being anticipated by Olson have been fully considered and are persuasive. The rejection of claims 1-14, 18, 20-29, and 31-33 has been withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11-14, 20-22, 24-29 remain and claims 18 and 31, 32, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoon et al. (US Patent 6,472,375). Hoon teaches a

Art Unit: 1635

viral liposome vector comprising fused HVJ, which contain viral envelope, with nonviral reagents for delivery of nucleic acid encoding a tumor-associated antigen into a tumor or an organ (column 3, lines 5-9, column 13, line 29, and Fig. 1). Hoon further teaches a pharmaceutical composition or a kit comprising the viral liposome vector (column 2, lines 65-67 and column 3, lines 20-22).

Applicant's arguments filed 2/19/03 have been fully considered but they are not persuasive. The product claims read on the vector taught by Hoon. Hoon teaches a gene transfer vector comprising an exogenous gene encapsulated in a virus envelope vector (see Figure 1).

Claims 1-9, 11-12, 16, 18, 20-22, 30, 31, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramani et al. (PNAS, 95:11886-18890, 1998). Ramani teaches a F-virosomes (Sendai virus) containing pCIS3CAT or pBVLuc DNA (page 11886). The plasmid was incubated with detergent solubilized fraction of Sendai virus containing its envelope. Ramani further teaches delivering the F-virosomes to a liver in mice (abstract).

Applicant's arguments with respect to claims 1-12, 18, 20-29, and 31-33 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

Applicant's arguments, see paper no. 9, filed 2/19/03, with respect to 103(a) rejection have been fully considered and are persuasive. The rejection of claims 19 and 34-36 has been withdrawn.

Art Unit: 1635

Applicant's arguments, see paper no. 9, filed 2/19/03, with respect to 103(a) rejection have been fully considered and are persuasive. The rejection of claims 15-17 and 30 has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

*Scott D. Priebe*  
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PRIMARY EXAMINER